

REMARKS

With the entry of the preceding amendments, claims 13 and 15-20 are pending, claims 1-12 and 14 being cancelled, claim 13 being amended, and claims 15-20 being added.

At the outset, Applicants direct the Examiner's attention to the specification of this reissue application where corrections from two Certificates of Correction have been made. Specifically, at Col. 1, line 16, a statement regarding federally sponsored research and development has been added. At Col. 1, line 17, a paragraph regarding "Technical Field" has been added. At Col. 2, line 27 the reference citation was corrected to "84:401-408". At Col. 6, line 56 "lypolizates" was corrected to "lyophilizates". At Col. 9, line 11 "(SUB)" was corrected to "(KUB)". At Col. 9, line 36 "illnes" was corrected to "illness". At Col. 13, line 47 "Bisphosphonates" was corrected to "Bisphosphonates (mg/day)".

Claims 1-12 and 14 are cancelled without prejudice to Applicants' right to prosecute and/or enforce any other applications or patents which have the same or similar subject matter.

Claim 13 as amended is subgeneric to originally issued claim 1, and thus does not enlarge the scope of the claims of the original patent. Newly added claims 15-20 depend from claim 13, and thus are not broader than claim 13 as amended. Specifically, claim 13 has been amended to recite a method for treating the pathological effects of hyperparathyroidism secondary to end stage renal disease comprising administering a non-oral dosage form of various vitamin D analogs, with the analog lowering elevated or maintaining lowered serum parathyroid hormone levels in a human. Support for this amendment can be found in the specification of the '386 Patent at Col. 3, lines 41-48 and Col. 6, lines 40-16.

Newly added claim 15 is directed to the method of claim 13 wherein the analog is administered in combination with at least one agent characterized by the agent's ability to reduce loss of bone mass or bone mineral content. Support for new claim 15 can be found in the specification of the '386 Patent at Col. 13, lines 12-35. Newly added claim 16 depends from claim 15 and recites specific agents which reduce loss of bone mass or bone mineral content. Basis for new claim 16 can be found at Col. 13, lines 29-33. Newly added claim 17 depends from claim 13 and further delineates that the analog is administered in a dosage amount of about 1 µg to 100 µg per week. Support for new claim 17 can be found at Col. 3, lines 61-62. Newly added claim 18 depends from claim 13 and sets forth that the analog is administered parenterally

in a dosage amount of about 1 µg to 30 µg given 1 to 3 times per week. Basis for new claim 18 can be found at Col. 6, lines 45-46. Newly added claim 19 is directed to the method of claim 13 wherein the analog is co-administered with a calcium-based phosphate binder. Support for new claim 19 can be found at Col. 12, lines 41-45. Newly added claim 20 depends from claim 13 and further delineates that the analog is 1α-OH-vitamin D₂. Basis for new claim 20 can be found at Col. 13, line 57.

Applicants respectfully submit that no new matter has been added by these amendments.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Teresa J. Welch", is written over a horizontal line.

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